

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE)
LITIGATION)
) MDL No. 1456
) Civil Action No. 01-12257-PBS
)
THIS DOCUMENT RELATES TO:) Subcategory No. 06-11337-PBS
) (Docket# 6316)
<i>United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 07-CV-11618-PBS</i>) Hon. Patti B. Saris
)

**PLAINTIFF'S RESPONSE TO ABBOTT'S LOCAL RULE 56.1 STATEMENT OF
UNDISPUTED MATERIAL FACTS IN SUPPORT OF ABBOTT'S MOTION FOR
PARTIAL SUMMARY JUDGMENT**

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Pursuant to Local Rule 56.1, Plaintiff, Ven-A-Care of the Florida Keys, Inc., hereby submits its Response to Abbott's Statement of Undisputed Material Facts in Support of Abbott's Motion for Partial Summary Judgment. To the extent any statement of fact herein is genuinely disputed, Plaintiff reserves the right to argue that the disputed fact is not material. To the extent any statement of fact herein is undisputed, it is undisputed purely for Abbott's Motion for Partial Summary Judgment and Plaintiff reserves the right to dispute any statement in future proceedings.

I. THE PARTIES

1. The parties to this litigation are Ven-a-Care of the Florida Keys, Inc., ("Ven-a-Care") and Defendant Abbott Laboratories Inc. ("Abbott"). Ven-a-Care's principal officers and directors are John M. Lockwood, M.D., Zachary Bentley, Luis Cobo, and T. Mark Jones. (Case No. 07-CV-11618, Docket #6442 -Abbott SOF Exh. 1 ¶¶ 12 and 16.)

II. VEN-A-CARE'S COMPLAINTS AND VEN-A-CARE'S INFORMATION UNDERLYING ITS FALSE CLAIMS ACT ALLEGATIONS

2. In 1995, Ven-a-Care filed a False Claims Act suit in United States District Court for the Southern District of Florida under seal against various drug manufacturers, including Abbott. (Case No. 95-CV-1354.) This case was brought by Ven-a-Care concerning certain Abbott multi-source drug products known as injectables and fluids. These drugs were generally the responsibility of an Abbott division known as the Hospital Products Division ("HPD"). The United States ultimately intervened in this case. Discovery is complete and summary judgment briefing is pending in this case. (See Docket #6442-Abbott SOF Exh. 2.)

3. On April 10, 2000, Ven-a-Care filed a False Claims Act suit under seal in United States District Court for the District of Massachusetts against various drug manufacturers, but

not Abbott. On February 15, 2001, Ven-a-Care filed an amended complaint in this case pending in Massachusetts and brought claims concerning certain Abbott multi-source drug products known as Erythromycin (“Ery”) drug products. (See Anderson Dec. Exh. 2 - 2/15/01 First Amended Complaint.) These oral drugs were generally the responsibility of an Abbott division known as the Abbott Pharmaceutical Products Division (“PPD”). (See Docket #6442 -Abbott’s SOF Exh. 4.)

4. This referenced First Amended Complaint named six (6) Ery drugs which amounted to thirteen (13) National Drug Codes (“NDCs”). Ven-a-Care provided a “description of the False Claims scheme” in paragraph 60 stating, “DEFENDANTS are each liable under the False Claims Act because they caused the States’ Medicaid Programs to pay claims for certain of their generic prescription drugs in exorbitant amounts, far in excess of the reasonable reimbursement permitted under the applicable statutes and regulations.” (See Anderson Dec. Exh. 2 - 2/15/01 First Amended Complaint.) Ven-a-Care also explained how AWP, along with WAC, was used in calculating Medicaid drug reimbursements. *Id.* at ¶¶ 30 – 32.

5. At this time, Ven-a-Care brought claims related to how several enumerated state Medicaid programs used published WAC pricing in setting drug reimbursements. *Id.* at ¶ 2.

6. On February 1, 2002, Ven-a-Care amended and filed a Second Amended Complaint adding an allegation regarding Abbott Direct prices and their impact on California Medicaid. (Docket #6442 - Abbott SOF Exh. 9 ¶ 141.)

7. On February 15, 2005, Ven-a-Care filed its Third Amended Complaint. Ven-a-Care described Abbott’s conduct as “knowingly making false or fraudulent representations about prices and costs of the drugs . . . which Abbott knew would be utilized by Medicaid.” See Anderson Dec. Exh 6 (Third Amended Complaint 2/15/05 at ¶192). Ven-a-Care set forth

specific AWP prices which were allegedly fraudulent. (See ¶ 194).

8. In the Second Amended Complaint and the Third Amended Complaint Ven-a-Care named additional formulations of the underlying Ery drug compound. See Anderson Dec Exh. 5 and 6.

9. The AWP price shown for the Ery NDC # 00074-6346-53 in Ven-a-Care's Third Amended Complaint Exhibit 1 (Anderson Dec. Exh 6) was exactly 25% greater than the published WAC for that same drug shown in the same complaint through Exhibit 9 (\$52.25 WAC shown in Exhibit 9 multiplied by 1.25 equals the \$65.31 AWP shown in Exhibit 1). Ven-a-Care states that Abbott does not dispute it routinely published AWP prices to First Data Bank, Redbook and Medispan which were 25% greater than the WACs Abbott published for respective drugs. *See* Anderson Dec. Exh 11 (Fiske Tr. 02/17/09) and Anderson Dec. Exh 15 (Parker Tr. 02/19/09).

10. In response to Abbott's SOF paragraph 42, Ven-a-Care admits it has not submitted a pharmaceutical claim for reimbursement payment since approximately 1998. However, Ven-a-Care's claims are based upon market pricing information to which Ven-a-Care had direct and independent insider access for many years subsequent to 1998. *See* Anderson Dec. Exh 24 (John Lockwood Tr. 12/06/07 at 195:11 -198:22)

11. In response to Abbott's SOF paragraph 43 and 44, Ven-a-Care does not contest that it did not have a specific conversation or incident with an Abbott employee who marketed the spread to Ven-a-Care on the Ery products. However, Ven-a-Care is aware of the mechanisms by which reimbursement pricing information is marketed to pharmacies; including Ven-a-Care. *See* Anderson Dec Exh 3 (John Lockwood Tr. 04/23/09 at 104:12 - 115:21) and *see* Anderson Dec Exh 25 (12/4/06 Plaintiff's Response to Interrogatory 6).

12. In response to Abbott's SOF paragraph 45, Ven-a-Care states that it does have market knowledge concerning how drug manufacturers, including Abbott, cause prices utilized in drug reimbursement to be published and then in turn considered by pharmacies in the selection of generic drugs. *See* Anderson Dec Exh 3 (John Lockwood Tr. 04/23/09 at 86:3 - 89:19 and at 93:11 - 102:14).

13. In response to Abbott's SOF paragraph 46, Ven-a-Care states that it most likely did purchase Ery drugs, but it lost drug purchase invoices from the 1990's due to severe roof damage to its premises during Hurricane Georges. *See* Anderson Dec Exh 22 (John Lockwood Tr. 01/17/08, 361: 13-19) and Anderson Dec Exh 23 (John Lockwood Tr. 07/27/09 at 45:11-17). Ven-a-Care's claims are based upon market pricing information to which Ven-a-Care had insider access for many years. *See* Anderson Dec. Exh 3 (John Lockwood Tr. 4/23/09 at 35:15-38:6).

14. In response to Abbott's SOF paragraph 47, Ven-a-Care does not dispute that Abbott has quoted the Ven-a-Care testimony which Abbott selected accurately; however, Ven-a-Care also testified as follows regarding the process by which it conducted its analysis into the Ery prices and explained the pricing manipulation which it discovered, in part, below. This analysis required access to industry insider pricing information and involved an ability to contrast the Ery products with other Abbott PPD products

5 thing that stood out most was that when I
6 looked at Abbott's reported wholesale acquisition
7 cost, their WAC price for these drugs, that that
8 price in many circumstances was way above the price
9 that I could buy this drug from McKesson at their --
10 it's termed a lot of different things, they're
11 wholesale catalog list price, their noncontract
12 price, meaning the price that the wholesaler would
13 sell that drug to you without a contract, just a
14 simple relationship, wholesaler/pharmacy
15 relationship, and that I could buy these drugs for
16 less than what Abbott was reporting that they were

17 selling the drugs to the wholesalers for.
18 And that was not the situation with
19 Abbott's other brand drugs, meaning that the prices
20 that I could buy -- I don't know. Let's take a drug
21 like Biaxin, perhaps, or Depakote. The catalog list
22 price, noncontract price for those drugs was very

1 close to, similar to, or identical to the reported
2 wholesale acquisition cost on those drugs. But for
3 these Ery drugs, that was not the case.

(See Anderson Dec. Exh 3 (John Lockwood Tr. 04/23/09 14:7 – 15:16)

15. In response to Abbott's SOF paragraph 48 – 51, Ven-a-Care states that it conducted significant analysis of electronic databases of insider pharmacy pricing in order to identify and allege False Claims Act claims against Abbott concerning the PPD Ery drugs. Ven-a-Care representative, Dr. John Lockwood, clearly stated such electronic data analysis was first available to Ven-a-Care once Ven-a-Care moved from paper McKesson pricing offers to McKesson electronic pricing databases. See Anderson Dec. Exh 3 (John Lockwood Tr. 04/23/09 at 222: 12 - 225: 22). Ven-a-Care acquired its electronic version of Econolink in March 2000 and Ven-a-Care did share a copy of Econolink with attorneys representing the United States in January 2001. (See Docket #6442- Abbott SOF ¶ 11.)

III. ALLEGED FCA PUBLIC DISCLOSURES REGARDING ERY DRUGS¹

16. In response to Abbott's SOF paragraph 25, Ven-a-Care states this 1984 information does not provide any indication of drug pricing generally, or Ery-specific, in the mid

¹ Ven-a-Care deals with these documents in much greater detail in its Combined Response to Motions to Dismiss by Abbott, Dey and Roxane as well as in its Response to Abbott Motion to Dismiss in this instant case. Ven-a-Care objects to Abbott's effort to include these items in a Local Rule 56.1 Statement of Facts when these items are actually the focus of separate Motions to Dismiss for Lack of Subject Matter Jurisdiction. Ven-a-Care reserves its right to fully address these materials in the context of the Motion to Dismiss in showing these items are not FCA "public disclosures" and that Ven-a-Care is an Original Source of the information underlying its allegations.

or late 1990's because it precedes such timeframe by a decade. Second, the information is extremely limited. The OIG noted,

“HCFA has periodically supplied State Medicaid agencies with invoice price level data designed to assist them in evaluating their Estimated Acquisition Cost (EAC) limits. However, the data supplied has not been an adequate substitute for AWP and may have been counterproductive since the amounts furnished have often been very similar to the AWP for individual drugs. The statistics gathered by HCFA are based on drug prices shown on invoices. These prices are generally list prices and do not reflect any . . . discounts.” (emphasis added)

(See Docket #6442 (Abbott SOF- Ex. 12 at p. 10,193.)

Thirdly, Ven-a-Care disputes any Abbott Ery pricing information was set forth whatsoever. The acronym “EES” did not identify the drug product as an Abbott drug product. No Abbott name or Abbott labeler code was set forth. (Docket #6442-Abbott SOF Ex. 12 at 10.203.) Ven-a-Care further objects Abbott's inappropriate effort to bootstrap this “EES” reference with an unfounded affidavit which is not predicated on personal knowledge and is rife with speculation as to other person's state of mind.

17. In response to Abbott SOF paragraph 26, Ven-a-Care states that the Colorado letter cited by Abbott is the best evidence of its contents. This letter does not identify any Ery prices or reimbursement spreads. (Docket #6442-Abbott SOF Ex. 13.) Furthermore, this letter does not provide any information at all about Abbott or the pricing discrepancies of any Abbott product. *Id.*

18. Ven-a-Care does not dispute that on July 5, 1987, the *Lexington Herald-Leader* published an article “*Drug Industry Over Charging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars.*” Abbott has paraphrased and in other instances selectively quoted from that article; the entirety of the article referenced is the best evidence of its content. Ven-a-

Care notes the article is and contains hearsay. Ven-a-Care disputes the materiality of the article to Abbott's liability under the FCA as there is no evidence that responsible officials in Abbott's pricing or marketing department ever read this or similar articles or the "federal studies" reported on, nor is there any evidence Abbott personnel relied on such information in setting prices for drugs. (*See* Anderson Dec. Exh 11 (Joseph Fiske Tr. 2/17/2009 at 16 – 22). Finally, the article is far from clear as to any conclusion about the drug pricing. For instance, a vice-president of the National Assoc. of Retail Druggists was quoted saying AWPs "are realistic approximations for the prices pharmacies are getting across-the-board." (See Docket #6442-Abbott SOF Ex. 14 at 4.) Another pharmacy trade group stated, "we haven't seen any laws broken . . . (and) use of the sales technique (the spread) was extremely limited." *Id.* at 7. These comments certainly do not indicate or allege AWP fraud, rather they dispute the existence of such fraud. Instead, the reporter noted that pharmacists claimed AWP prices were "too low" rather than "too high" stating that "(t)hey argue that they don't make much profit on Medicaid." *Id.* at 9. Further, the article predates the fraud scheme at issue and a public disclosure cannot factually or legally be a prediction of the future.

19. In response to Abbott's SOF paragraph 28, Ven-a-Care does not dispute that in March 1991 the HHS-OIG issued a report entitled "Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs in the United States and Canada." Ven-a-Care does not dispute that this report shows the "Ontario" price of an Ery product. This information does not indicate the prices at which any American pharmacy could purchase Ery. In fact, the pricing of drugs in other countries compared to America is a matter of much controversy not at issue in this case. Ven-a-Care disputes the materiality of the report under the FCA. First, the report does not mention Abbott or refer to any Abbott Ery. Second, the Abbott's 30(b)(6) designee testified that

in setting its AWPs Abbott did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Abbott's price reporting practices. *See* Anderson Dec. Exh 11 (Joseph Fiske 2/17/09 at 16 – 22).

20. In response to Abbott's SOF paragraph 29 and 30 concerning the July 31, 1992 Congressional hearing, Ven-a-Care states that in the context of both the Abbott Ery MPSJ and the Abbott MTD, Abbott has tried to trick the Court with a false citation to this July 1992 Congressional hearing record. (See an incomplete copy of Congressional record filed by Abbott as Abbott SOF Exh. 16 (SOF MPSJ) and Abbott MTD Exh. 11 (MTD); (both are the same 11 pages (cover and pp. 302-310) of the 7/92 record).) Ven-a-Care attaches the complete document which Abbott did not file. See Anderson Dec. Exh.26 (7/31/92 Complete Congressional Record-Prescription Drug Rebate Program Testimony). Abbott cited to a hidden page which it did not file and also hid the other pages which directly contradicted its misrepresentations about the nature of these so-called contract prices. Abbott states that the National Association of Retail Druggists ("NARD")² had "submitted a comparison of the contract prices (available to members of its organization) and published AWPs." (See Abbott SOF ¶ 29.) This an absolute lie. The prices presented by NARD were presented for exactly the opposite proposition. NARD presented these prices as contract prices available to hospitals, which were **not available** to NARD's members, retail pharmacies. The prices shown in the price list at pp. 302-310 were actually obtained by NARD from a non-member known as Prucare and were represented by NARD to Congress to be "hospital prices." See Anderson Dec. Exh.26 (7/31/92 Complete Congressional Record-Prescription Drug Rebate Program Testimony at p. 295.) NARD clearly stated these "hospital" prices "were discounted beyond the amount (AWP-15%) that might be

² NARD represented "40,000 independent pharmacies" which provided "nearly 85% of the Medicaid pharmaceutical services" throughout the nation at that time. Id. at 280.

available to retail pharmacists . . . (a)ny way you slice it our members our getting a raw deal.”

See Anderson Dec. Exh.26 (7/31/92 Complete Congressional Record-Prescription Drug Rebate Program Testimony at p. 295 and 301). (Note: Both of these pages of the July 1992 Congressional record were hidden from Ven-a-Care and the Court by Abbott.) In its gamesmanship, Abbott has inadvertently cited to public information which clearly shows that in the 1990’s Congress was not aware of any mega-spreads or large discounts off of AWP on drugs. Instead, to the contrary a leading trade group representing tens of thousands of pharmacies who dispensed almost all of the pharmaceuticals provided to Medicaid patients, point-blank swore to Congress that they could not obtain large discounts which were available to others like hospitals and HMOs. Instead of being told retail pharmacy prices were much lower than AWP and Direct, Congress was actually told by the National Assoc. of Retail Druggists’, V.P. of Govt. Affairs and General Counsel, that “our members are getting a raw deal” and that “multitier pricing . . . provides mail order, drug vendors, nursing homes, HMOs, hospitals, and many other for-profit pharmacies significant competitive advantages to the detriment of independent retail pharmacy.”

See Anderson Dec. Exh.26 (7/31/92 Complete Congressional Record-Prescription Drug Rebate Program Testimony at p. 286 and 301).

21. No information in Abbott’s selectively limited Exhibit 16 (also marked as Exhibit 11 by Abbott in connection with its Motion to Dismiss) indicates Prucare is a pharmacy, much less a retail pharmacy. *Id.* To the contrary, not only does the full copy of the document explicitly show otherwise, but public information also puts the lie to Abbott’s representation that “Prucare” was a retail pharmacy because a few internet searches PruCare appears to be a hospital and/or insurance company operating, at least in part, as a Health Maintenance Organization (“HMO”). See <http://www.inovus.com/clients.htm>; see also <http://www.inomax.com/pdf/R5->

IMK-111-00369.pdf.

22. HMO pricing or other non-pharmacy pricing reveals nothing about the retail pharmacy pricing upon which Ven-a-Care's allegations were founded and which Ven-a-Care brought forward to the government regarding Ery. HMOs are able to maintain closed formularies thereby exerting bargaining power in their negotiation of drug prices. (See Anderson Dec Exh 34 - Abbott MTD Exhibit 7 pp. 2-3). Medicaid programs operate open formularies which do not provide this power.

23. In response to Abbott's SOF paragraph 31, Ven-a-Care does not dispute that on August, 4 1997, the OIG issued a report entitled *Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription Drug Products*.³ Ven-a-Care disputes the materiality of the report to Abbott's liability under the FCA, however. First, while the report workpapers include a mention of a specific type of Ery product, no mention of Abbott or any identification of an Abbott NDC is provided. Importantly, this underlying "workpaper" information is not set forth in the actual public report and there is no evidence the "workpaper" information was in any way made available to the public. Second, Abbott's 30(b)(6) designee testified that in setting its AWPs Abbott did not review, consider or rely on any reports published by the federal government as indications that the federal government was aware of or approved Abbott's price reporting practices. See Anderson Exhibit 11 (Joseph Fiske Tr. 2/17/09 at 16-22) Finally, no language in the report itself indicates approval of AWPs that exceeded providers' actual acquisition costs.

24. In response to Abbott's SOF paragraph 32 concerning a 1996 *Barron's* article, Ven-a-Care states no information concerning the pricing of any companies' Ery drugs was set forth, nor was any specific information provided about Abbott pricing of Ery drugs. (See Abbott

³ As shown in Ven-a-Care's Combined Response and Original Source showing, Ven-a-Care was the source of much information made a part of this report.

SOF Exh. 18.) The entirety of the article referenced is the best evidence of its content. This article contains inadmissible hearsay.

25. In response to Abbott's SOF paragraph 33 concerning a Medicaid Pharmacy Administrators Symposium, Ven-a-Care notes that this document only pertains to issues related to Medicaid rebate payments to be made by drug manufacturers to Medicaid programs. (See Docket #6442- Abbott SOF Exh. 19.) Ven-a-Care disputes the admissibility of this proffered information because Medicaid rebate payments under OBRA 1990 are separate from the FCA claims drug pricing claims brought in this case. The entirety of the article referenced is the best evidence of its content. This article contains hearsay.

26. In response to Abbott's SOF paragraph 34 concerning a May 1998 OIG report titled, "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs", Abbott has correctly, but selectively, quoted portions of this document. This report does not contain any information about Abbott or any Abbott product such as the Ery products named in this case. (See Docket #6442- Abbott SOF Exh. 20.) This report does not indicate any approval by the United States of Abbott's price-reporting practices with respect to the Ery products. *Id.*

27. In response to Abbott's SOF paragraph 35 concerning a November 29, 2001 HHS-OIG report titled, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Texas Health and Human Services Commission", Ven-a-Care notes this report does not identify any pricing on Abbott drugs, including the Erys, and does not even mention Abbott. (See Docket #6442 - Abbott SOF Exh. 21.) This report does not indicate any approval by the government of any Abbott price-reporting practice. *Id.* Abbott did not rely upon or otherwise utilize this or any other report in setting, publishing or marketing

any pricing information. *See* Anderson Dec. Exh 11 (Joseph Fiske Tr. 2/17/09 at 16-22).

28. In response to Abbott's SOF paragraph 36 concerning a March 14, 2002 HHS-OIG report titled, "Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products", Ven-a-Care states this report does not identify any pricing on Abbott drugs, including the Erys, and does not even mention Abbott. (See Docket #6442-Abbott SOF Exh. 23.) This report does not indicate any approval by the government of any Abbott price-reporting practice. *Id.* Abbott did not rely upon or otherwise utilize this or any other report in setting, publishing or marketing any pricing information. *See* Anderson Dec Exh 11 (Joseph Fiske Tr. 2/17/2009 at 16 – 22).

29. In response to Abbott's SOF paragraph 37 regarding work done in Idaho for Myers and Stauffer, Ven-a-Care states "Exhibit B" of this document shows many drugs were bought by pharmacies at prices about 16% less than AWP. (See Docket #6442-Abbott SOF Exh. 24 at Exh. B.)⁴ This report does not indicate any approval by the government of any Abbott price-reporting practice. *Id.* Abbott did not rely upon or otherwise utilize this or any other report in setting, publishing or marketing any pricing information. *See* Anderson Exhibit 11 (Joseph Fiske Tr. 2/17/2009 at 16 - 22).

30. In response to Abbott SOF paragraph 38, Ven-a-Care states this report does not identify any pricing on Abbott drugs, including the Erys, and does not even mention Abbott. (See Docket #6442- Abbott SOF Exh. 25.) This report does not indicate any approval by the government of any Abbott price-reporting practice. *Id.* Abbott did not rely upon or otherwise utilize this or any other report in setting, publishing or marketing any pricing information. *See*

⁴ Local and state information such as this Idaho material does not satisfy the statutory requirements of the FCA to constitute a public disclosure and is not a "federal" administrative report. *U.S. ex rel. Wilson v. Graham Co. Soil*, 528 F.3d 292, 296 (4th Cir. 2008)

Anderson Dec. Exh 11 (Joseph Fiske Tr. 2/17/2009 at 16 – 22).). Local and state information such as this Kentucky material does not satisfy the statutory requirements of the FCA to constitute a public disclosure and is not a “federal” administrative report. *U.S. ex rel Wilson v. Graham Co. Soil*, 528 F.3d 292, 296 (4th. Cir. 2008).

31. In response to Abbott SOF paragraph 39, Ven-a-Care states this report does not indicate any approval by the government of any Abbott price-reporting practice. (See Abbott SOF Exh. 26). Abbott did not rely upon or otherwise utilize this or any other report in setting, publishing or marketing any pricing information. See Anderson Dec. Exh 11 (Joseph Fiske Tr. 2/17/2009 at 16 – 22). There is no proof that the specific information from or underlying the report was ever “public” made via a source described in and as defined by the False Claims Act, 31 U.S.C § 3130(e). Such local and state information such as this Wyoming material does not satisfy the statutory requirements of the FCA to constitute a public disclosure and is not a “federal” administrative report. *U.S. ex rel Wilson v. Graham Co. Soil*, 528 F.3d 292, 296 (4th. Cir. 2008).

32. In response to Abbott SOF paragraph 40, Ven-a-Care states this report does not identify any pricing on Abbott drugs, including the Erys, and does not even mention Abbott. (See Docket #6442- Abbott SOF Exh. 27). This report does not indicate any approval by the government of any Abbott price-reporting practice. *Id.* Abbott did not rely upon or otherwise utilize this or any other report in setting, publishing or marketing any pricing information. See Anderson Dec. Exh 11 (Joseph Fiske Tr. 2/17/2009 at 16 - 22). Local and state information such as this Louisiana material does not satisfy the statutory requirements of the FCA to constitute a public disclosure and is not a “federal” administrative report. *U.S. ex rel Wilson v. Graham Co. Soil*, 528 F.3d 292, 296 (4th. Cir. 2008).

33. In response to Abbott SOF paragraph 41, Ven-a-Care states this report does not identify any pricing on Abbott drugs, including the Erys, and does not even mention Abbott. (See Abbott SOF 28). This report does not indicate any approval by the government of any Abbott price-reporting practice. *Id.* Abbott did not rely upon or otherwise utilize this or any other report in setting, publishing or marketing any pricing information. See Anderson Dec. Exh 11 (Joseph Fiske Tr. 2/17/2009 at 16 - 22).). Local and state information such as this California material does not satisfy the statutory requirements of the FCA to constitute a public disclosure and is not a “federal” administrative report. *U.S. ex rel Wilson v. Graham Co. Soil*, 528 F.3d 292, 296 (4th. Cir. 2008).

34. In response to Abbott’s SOF paragraph 52, Ven-a-Care states that the Ery drugs were priced similarly and uniquely by Abbott PPD. (See Anderson Dec. Exh. 27- Russell Lehn Tr. at 62:17-63:1; 64:14-65:5.)

IV. ABBOTT’S PRICE PUBLISHING PRACTICES

35. In response to Abbott’s SOF paragraphs 53 – 57, Ven-a-Care references its SOF in Support of Ven-a-Care’s Motion for Partial Summary Judgment ¶¶ 6-8; 17-18 (Docket #6417). Also, in the 1990’s, Abbott’s PPD consistently reported AWPs, WACs, and Direct prices for its products, including the Erys, directly to the pricing compendia. (See Anderson Dec. Exh 15 (Theresa Parker 02/19/2009 at 82:9 – 85:8). In 2001 or so Abbott started naming these AWPs it set as “estimated” AWPs. The Abbott corporate representative, Joe Fiske, testified this additional language was added to prevent “confusion” and admitted that prior to that time Abbott did nothing to indicate in its pricing notifications of AWP to First Data Bank that Abbott was only providing a so-called estimate.

12 Q. I notice on the third page of Exhibit 9 is

13 the beginning of a price list, correct?

14 A. Yes.

15 Q. And there's -- there's three different
16 types of prices listed. One is list price, the other
17 is case price, and the last one is AWP price,
18 correct?

19 A. Yes.

20 Q. And so those would be prices that Abbott
21 had set and, in turn, communicated to the data
22 vendors, correct?

23 A. Yes.

24 Q. How did Abbott --

25 A. Well, we communicated an estimated AWP. We

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1 set the WAC and the list price.

2 Q. Where --

3 A. The WAC price being the case price.

4 Q. Where is the AWP information noted to be an
5 estimate?

6 A. I'm telling you that it was always an
7 estimate. We actually changed the column at a
8 subsequent date to read that it was an estimate to
9 avoid any confusion.

10 Q. How might it be confusing if the AWP
11 weren't noted to be an estimate?

12 A. I don't have an answer for that question.

13 Q. Do you agree that to the extent Abbott was
14 reporting, quote, "AWPs" to the data vendors, it
15 would appear that Abbott is setting the AWPs?

16 MR. BERLIN: Objection, form.

17 Objection, scope.

18 A. I don't agree with that.

19 Q. (BY MR. ANDERSON): What information would
20 indicate that Abbott is not controlling this AWP?

21 A. Pardon me?

22 MR. BERLIN: Objection, form.

23 Objection, scope.

24 Q. (BY MR. ANDERSON): What -- what
25 information would indicate that Abbott is not

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1 controlling the setting of these AWPs?

2 MR. BERLIN: Objection, form.

3 Objection, scope.

4 A. There's no information on this sheet that

5 says that.

(See Anderson Dec. Exh 11 (Joseph Fiske Tr. 02/17/2009 at 136-139)).

36. In response to Abbott's SOF paragraphs 58, Ven-a-Care does not contest Abbott's quotation of their selected definition of "List price". However, Ven-a-Care does note that Abbott is unclear in its SOF as to which Abbott price term, AWP, Direct (ie., "List"), or WAC price, and for which drugs Abbott purports to be its "List price." Abbott utilized WAC prices for most PPD products as the usual, actual transaction prices. Anderson Dec. Exh. 28 (Joseph Fiske Tr. 3/22/07 316:22-317:4.) However, as noted at length in Ven-a-Care SOF in Support of Ven-a-Care's MPSJ, Abbott did not treat the WAC prices for its Ery products similar to the other PPD division products and that fact is a key aspect of Abbott price misrepresentations for the Erys.

37. In response to Abbott's SOF paragraph 59, Ven-a-Care does not dispute the accuracy of Abbott's selected quotations regarding WAC. However, Ven-a-Care notes that this definition, which became effective in 2005, applies to Medicare and is focused upon brand (ie., "single-source") drugs. 42 U.S.C. §1395w-3a(b)(4). This context is important because the purpose behind WAC, as defined by the MMA, is to use WAC as a proxy for actual average sales prices. The weighted average WAC may be used I the Medicare arena when it is lower than the weighted average ASP or there is no sales history of actual sales prices. *Id.*; see also 42 U.S.C. §1395w-3a(c)(4). This reference to WAC presumes WAC reflects real transaction prices rather than functions as a mere list price which is not actually the basis for net transaction. Also, WAC has been defined as a "net" price in both U.S. Dept. of Commerce and HCFA publications. (See Anderson Dec. Exh 29- Dept. of Commerce report p. 4 and Anderson Dec Exh. 30 - 1994 HCFA Spring Review p. 26). This Court has previously issued a ruling concerning the meaning of the acronym "WAC". Specifically, the Court noted, "(n)umerous sources within the industry

defined WAC as the price wholesalers actually paid. Significantly, the practice of FDB was to report its WACs under the heading of ‘WHLNET’ or ‘WHN’” which stood for “net”.

Massachusetts v. Mylan, 608 F.Supp.2d 127, 154 (D. Mass. 2008). Abbott not used WAC consistently for its PPD products. For most PPD products, WAC is actually reflective of net transaction prices while for the PPD Ery products, the published WAC was not. (See Docket #6417-Ven-a-Care’s SOF ¶¶ 6-8; 17-18.) This dichotomy was a result of the publication of misleading WAC pricing for the Erys and the concealment of actual gross invoice wholesale invoice prices known as Base Deal pricing on the Erys. *Id.*; see also Docket #6417-Ven-a-Care’s SOF 19, 20, 37, 44 and 46. Also, Abbott chose to publish list prices and, since it knew that they were substantially inflated for its Ery products, should have lowered the list prices or reported some other, non-misleading, price.

38. In response to Abbott’s SOF paragraph 60, Ven-a-Care states that Abbott admits its sales at published “WAC” prices for the Ery drugs were rare and this contrasted sharply with the other PPD drugs. (See Docket #6417- Ven-a-Care’s SOF ¶ 8 and 17). For the most highly utilized Ery NDC, the analysis of Dr. Duggan showed the published WAC was around \$28 for most the time period yet the prevailing wholesale costs were approximately \$10. (See Anderson Dec. Exh. 16 - Duggan Expert Report (Figure 1).

39. In response to Abbott’s SOF paragraph 61 and 79, Ven-a-Care does not dispute Abbott have reported AMP pricing information to CMS (f/k/a HCFA); however this AMP information was kept confidential by law and was not shared with state Medicaid programs for drug reimbursement purposes. This Court has already addressed this issue at length and found AMPs to have been confidential and “not to be revealed to third parties.” *Massachusetts v. Mylan*, 608 F. Supp. 2d 127, 152 (D. Mass. 2008). In this instance, the third parties would be the

state Medicaid programs because only the drug companies and CMS normally are privy to AMP information. Also, in this AMP context the Court noted, “even if you didn’t need Einsteinian quantitative skills . . . failure to do so does not equate to government knowledge or approval.”

Id.

40. In response to Abbott’s SOF paragraph 62, until 2001 Abbott did expressly report AWP prices for all PPD drugs, including the Erys, to price publishing compendia such as First Data Bank and Redbook. (See Anderson Dec. Exh.15 Theresa Parker Tr. 82:5-85:2; 90:24-91:4; see also Anderson Dec. Exh. 31- Fiske dep. Exh. 9.) Since 2001, Abbott has expressly reported “estimated” AWP prices to the same compendia. (See Anderson Dec. Exh. 11- Fiske 2/17/09 trans. pp. 136-139.) To Abbott’s knowledge, these “estimated” AWP values derived from Abbott have never differed from the AWP information published, in turn, by the compendia. *Id.* at 133:21-134:2.

41. In response to Abbott’s paragraph 63, Ven-a-Care states that Abbott did control the pricing published by the compendia for Abbott drugs, including the Erys. Abbott knew what the compendia would publish based upon the pricing which Abbott admittedly purposefully reported to the compendia. (See Docket #6417-Ven-a-Care’s SOF ¶ 14.) Abbott controlled the pricing published by the compendia for drug products. *Id.*; see also VAC SOF ¶ 6

42. In response to Abbott’s paragraph 64, Abbott knew the pricing it published for the Erys was inflated well above usual market pricing and knew such published prices were utilized for drug reimbursement, by Medicaid and others. (See Docket #6417 -Ven-a-Care’s SOF ¶¶ 8-9; 14-16.)

43. In response to Abbott's paragraph 65, senior Abbott personnel who reported to Kay Morgan testified that Kay Morgan did not have price-reporting responsibilities for Abbott. (See Anderson Dec Exh 15 -Parker 48:6-49:17).

44. In response to Abbott's paragraph 66, Ven-a-Care does not dispute Abbott correctly quoted the selected testimony. Ven-a-Care submits that other information evidences Abbott knowingly impacted drug reimbursement for the Ery products with awareness that its customers were interested in such reimbursement on such generic drugs. (See Docket #6417-Ven-a-Care's SOF ¶¶ 8-9; 14-16.)

V. MEDICAID REIMBURSEMENT

45. In response to Abbott's SOF paragraphs, 67 – 70, Ven-a-Care references its SOF in Support of Ven-a-Care's MPSJ ¶¶ 62-124 (Docket #6417). Ven-a-Care also notes that Federal Upper Limit ("FUL") and Maximum Allowed Cost ("MAC") prices simply operate as a maximum or ceiling price which caps reimbursement. Accordingly, FUL or MAC prices do not exclusively form the basis for Medicaid reimbursement, even when FUL or MAC prices are effective. As a function of state Medicaid programs almost universal use of "lower of" reimbursement methodologies, Abbott's reporting of truthful published prices which reflected market prices paid by pharmacies would have resulted in EACs lower than an applicable FUL or MAC for a given drug reimbursement calculation. See Anderson Dec. Exh 33-Declaration of Dr. Duggan ¶¶ 26, 29, and 31 .

46. In response to Abbott's SOF paragraph 71, Ven-a-Care does not dispute that some Erys were subject to FUL ceiling prices at times.

47. In response to Abbott's SOF paragraph 72, Ven-a-Care disputes Abbott's contention as stated. Abbott could and did impact Medicaid reimbursement by reporting inflated

published prices, even in situations where a FUL or state MAC maximum reimbursement cap was in place. Through the reporting of misleading published prices, Abbott caused reimbursement to be set at the ceiling level as opposed to the appropriately lower EAC level derived from the lower prices Abbott should have reported for the Erys. *Id.*

48. In response to Abbott's SOF paragraphs 73 – 77, Ven-a-Care does not dispute that CMS set FUL prices, but Ven-a-Care does not agree that the mechanics utilized in setting any FUL are relevant given that Ven-a-Care has refined its allegations and is only pursuing claims and damages arising from the above-discussed “lesser of” formulas. *Id.*; see also Anderson Dec. Exh. 16 - Duggan Expert Report p. 27 fn 19.)

49. In response to Abbott's SOF paragraphs 80 – 86, Ven-a-Care does not dispute that AMP has been enjoined from use as the basis of setting FUL prices. Pharmacies who supported this injunction did so because in their view AMP data are flawed and known to include discounts to entities, such as “mail-order” operations, which are outside of the retail (pharmacy) class of trade. (See Anderson Dec. Exh. 35 at p. 2) The method used to calculate the AMPs under the reimbursement system caused them to be materially lower than the prices generally and currently paid in the marketplace by retail pharmacies, creating the problem that is being further addressed. This has nothing to do with Medicaid rebate calculations. AMPs as calculated under the methodology are and were not available or useable for reimbursement purposes.

50. In response to Abbott's SOF paragraphs 87 – 92, Ven-a-Care simply states that Abbott's focus upon the mechanism for the setting and rationale behind setting MAC prices is not pertinent to Ven-a-Care's instant False Claims Act causes of action. Ven-a-Care compares the actual past reimbursement amounts paid to the amounts that would have been paid if new Abbott Ery NDC-specific EACs had resulted from lower prices being published by Abbott. The

foundation of this approach is the “lesser of” or “lower of” reimbursement methodologies utilizes by virtually all state Medicaid programs. Ven-a-Care does not seek to recalculate any FUL or state MAC prices based upon any of the allegedly false Abbott Ery prices. *Id.*; see also Anderson Dec. Exh. 16 - Duggan Expert Report p. 27 fn 19.)

51. In response to Abbott SOF paragraphs 93-96, Ven-a-Care disputes such by incorporating and referencing VAC SOF ¶¶ 57-61.

VI. EXPERT OPINIONS AND ANALYSIS OF DR. MARK G. DUGGAN, PH.D

52. In response to Abbott’s SOF paragraph 97, Ven-a-Care notes that Dr. Duggan now is acting as the Senior Economist for healthcare on the White House Council of Economic Advisors. See Anderson Dec. Exh 33 - Duggan Declaration 10/29/09 ¶ 1. Dr. Duggan holds degrees in electrical engineering from MIT and obtained his Ph.D in Economics from Harvard. *Id.* at ¶ 2. In 2004, Dr. Duggan was named a Alfred P. Sloan Foundation Fellowship which is a two-year award given to only six to eight economists in the entire field. *Id.* at ¶ 3.

53. In response to Abbott’s SOF paragraph 98, Ven-a-Care states that Dr. Duggan has published numerous studies and economic analyses concerning healthcare issues, including pharmaceuticals, in highly-reputed, peer-reviewed journals. *Id.* at ¶ 4-9. Dr. Duggan has never had any proffered expert opinions disallowed by any Court.

54. In response to Abbott’s SOF paragraph 101, Ven-a-Care states Dr. Duggan calculates a “difference” where he found such after replacing Abbott’s actual published prices with a scaled AWP connected with lower actual average transaction prices in Medicaid claims adjudication methodologies. *Id.* at ¶ 33.

55. In response to Abbott’s SOF paragraph 104, Ven-a-Care states that Dr. Duggan chose the states listed by Abbott not because of “high amounts of expenditures”, but because Dr.

Duggan “endeavored to perform the most detailed analysis on the state claims data for the states with the largest number of claims.” *Id.* at ¶ 17. This data produced from these 15 states was also found by Dr. Duggan to be reliable after testing. *Id.* at ¶ 17-19.

56. In response to Abbott’s SOF paragraph 105, Ven-a-Care notes that Table 28 of Dr. Duggan’s report evidences that for most of 15 states for which claims readjudication was conducted Dr. Duggan did analyze actual claims data for most of the entire period from 1994 to 2008. *Id.* at ¶ 12-15; Expert Report of Dr. Duggan at Table 28 (Anderson Dec. Exh 16).

57. In response to Abbott’s SOF paragraph 106, Ven-a-Care states that Dr. Duggan only calculated differences in situations where the applicable Medicaid reimbursement methodology implemented a “lesser of” or “lower of” formula for calculating reimbursement and a lower reimbursement resulted from using the scaled pricing determined from Abbott’s actual transaction pricing. See Anderson Dec. Exh 33-Duggan Declaration at ¶ 29-32.

58. In response to Abbott’s SOF paragraph 107, Ven-a-Care notes that Dr. Duggan generally did not need to conduct intra-state extrapolations because that claims-level data was very complete. *Id.* at ¶ 55. When such limited extrapolations were necessary they were done only after being tested by analyzing damages based upon an assumption that one year’s claims-level data did not exist. *Id.* at ¶ 55-58. This analysis determined that SDUD aggregate data causes a lower valuation of damages. *Id.* This is an example of the reliability and, if anything, conservative nature of Dr. Duggan’s extrapolations using SDUD data rather than other claims-level data when claims-level data was missing.

59. In response to Abbott’s SOF paragraph 108, Ven-a-Care states that Dr. Duggan’s extrapolation from the 15 states to the remaining states was predicated, in part, upon a

determination that the adjudication algorithms, the reimbursement per claim and other information indicated these two groups of states were very similar. *Id.* at ¶ 64.

60. In response to Abbott's SOF paragraph 109 - 112, Ven-a-Care disputes any explicit or implied notion that Dr. Duggan did not consider the impact of ceiling prices such as FUL, state MAC, or U&C pricing in the readjudication of Medicaid claims and calculation of damages. *Id.* at ¶ 29-32. Because "(w)ith rare exceptions, each state's adjudication methodology employed a 'lower of' logic such that . . . if defendant's (sic) AWP, when scaled in accordance with the applicable state methodology (ie., AWP-12%) resulted in a higher amount than any potential alternative price, it would be used as the basis of payment." *Id.* at ¶ 31. However, it is true that Dr. Duggan has not tried to recalculate the actual FUL or MAC prices themselves by replacing the "but-for" Abbott Ery published prices in the given FUL or MAC arrays utilized for setting such ceiling prices. See Anderson Dec. Exh 16 (Duggan "Ery" report. at p. 27 fn 19).

61. In response to Abbott's SOF paragraph 113, Ven-a-Care believes Abbott's characterization of the overall dollars in difference contrasted with the historical spending is misleading in that it ignores the 25% scaling factor utilized by Dr. Duggan. *Id.* at ¶ 20-22; 28. As cited extensively in the VAC SOF in Support of Ven-a-Care's Motion for Summary Judgment, this 25% factor reflects the mark-up from WAC utilized over many years to publish AWPs which was well known to Abbott. Furthermore, this misrepresentation by Abbott does not note the impact of ceiling prices to effectively mitigate or negate harm otherwise caused by Abbott's inflated published prices. As noted above, Dr. Duggan calculates damages from such ceiling prices down to the level of his alternative prices only in instances, and to the extent, such are less than those alternative prices.

62. In response to Abbott SOF paragraphs 114 and 115, Ven-a-Care agrees with Abbott that Dr. Duggan relied upon meticulously created summaries of all pertinent Medicaid claims adjudication methodologies and formulas. Dr. Duggan did not need to improperly inject subjective review of Abbott's selected Medicaid witness testimony in order to properly and accurately re-adjudicate Medicaid claims utilizing the approved methodologies of a given State as authorized by that state's respective legislative or regulatory bodies. Furthermore, Dr. Duggan's analysis utilizes averages such that oddities which increase or decrease calculated damages offset. See Anderson Dec. Exh 33- Duggan Declaration ¶ 54.

63. In response to Abbott SOF paragraphs 117 and 118, Ven-a-Care disputes that a critique of U&C charges made by pharmacies is relevant to ascertaining the damages caused by Abbott's manipulation and concealment of prices in order to cause inflated prices to be published.

64. In response to Abbott SOF paragraph 121, Ven-a-Care notes Dr. Duggan did use accepted sampling and testing techniques which are used in the field of economics and have been utilized by Dr. Duggan and others in other research in healthcare and other arenas. *Id.* at ¶ 5-10; 35.

65. Abbott SOF paragraph 122 is an inappropriate use of Local Rule 56.1 and Ven-a-Care objects accordingly. Ven-a-Care agrees Abbott's experts have logged criticisms, but Ven-a-Care absolutely disagrees with the substance and underlying foundation for all such criticisms.

66. In response to Abbott SOF 123, Ven-a-Care disputes Abbott's characterization and states Dr. Duggan did carefully consider the presence, of lack, of similarities between the two groups of states; the 15 prominent states with virtually comprehensive claims-level data and the remaining 34 states which also had respective Medicaid data. *Id.* at ¶ 46 and 52-54.

Furthermore, Dr. Duggan, if anything, took conservative steps to minimize calculations of damages such as extrapolating zero damages for New York Medicaid (where it used FUL exclusively) across the 34 states despite the fact that most of those 34 states did not only used FUL. *Id.* at ¶ 32.

67. In response to Abbott SOF paragraph 126, Ven-a-Care states that Dr. Duggan's analysis is not subject to bias such as those selected issues raised by Abbott in this paragraph because Dr. Duggan's analysis is based on averages which factor in variables which both increase and decrease damages calculations. *Id.* at ¶ 54. Also, the "Nebraska example" which allegedly results in an alleged over-estimation of damages, as Ven-a-Care understands it, ironically results in an underestimation of damage in the amount of \$20. (See Anderson Dec Exh 19 - second row of Dew spreadsheet).

VII. NO SETTLEMENT BY VEN-A-CARE OF CLAIMS OF THE UNITED STATES

68. In response to Abbott's SOF paragraph 128, Ven-A-Care does not dispute that "a settlement agreement was reached between the State of California, Ven-A-Care and Abbott" on December 9, 2008 and that Exhibit 106 is a copy of the Settlement Agreement and Release. Plaintiff specifically disputes the second sentence of paragraph 128 and states that the quoted language does *not* appear in the California Settlement Agreement.

69. The California Settlement Agreement (Abbott Ex. 106) did not settle or bar the claims asserted in this action on behalf of the United States. That settlement only released "Covered Conduct," which was expressly limited to claims asserted or that could have been asserted on behalf of California. (Ex. 106 at ¶ II (C)). Covered Conduct was also expressly limited to conduct that occurred during the Relevant Period for purposes of the California case, which does not cover the full period covered by this case.

The California Settlement Agreement further stated as follows:

The Qui Tam Plaintiff is the relator in sealed or unsealed federal action(s) against one or more of the Settling Defendants under the Federal False Claims Act, 31 U.S.C. § 3279 et seq. (the “FCA actions”) in which the same or similar price reporting conduct of the Settling Defendants is at issue. It is the intent of the parties that the Qui Tam Plaintiff not be able to share twice in the same recovery. The Qui Tam Plaintiff is hereby releasing its claims, if any, including any claims for attorney’s fees, expenses, or a Relator’s share, against the Settling Defendants for the Covered Conduct in the FCA actions, relating to the Medi-Cal program.

Id. Nothing in the California Settlement Agreement purported to release claims on behalf of the United States, which the Qui Tam plaintiff could not do as a matter of law. 31 U.S.C. § 3730(b). The sole matter released was the ability of the Qui Tam Plaintiff to share twice in overlapping recoveries, which necessarily contemplated the fact that there could be a Federal Recovery arising from the same matters.

70. In response to Abbott’s SOF paragraph 129, Ven-A-Care does not dispute that “[o]n September 8, 2008, Abbott reached a settlement with the State of Texas and Ven-A-Care” and that Exhibit 107 is a copy of the Settlement Agreement and Release. Plaintiff specifically disputes the second sentence of paragraph 129 and states that the two releases are not identical.

71. The present case was pending when the Texas settlement was reached. Hence, the covenant not to sue contained in the Texas agreement, which only covers future suits based on the Covered Conduct, is inapplicable both because of the fact that this case was pending and the limitations in the definition of Covered Conduct in that agreement.

72. In response to Abbott’s SOF paragraph 130, Ven-A-Care does not dispute that “Duggan did not remove [all] claims from California or Texas from his analysis.”

Respectfully submitted,

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